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**Summary of WG3 ad hoc 5 Jet Injectors**  
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## **Summary of WG3-Adhoc 5: Jet Injectors, 28 July, 1999**

### **I Safety**

- Tissue Response
- Pharmacokinetics
- Injection Site Trauma
- Pain Metrics
- Misuse/Injury of High Pressure Device
- Biocompatibility
- Cross contamination
  - Disposable components
  - Changing policies

#### **Accuracy Requirements**

### **II Preconditioning/Testing**

- Temperature
- Humidity
- Storage
- Stability and Aging
- Free Fall
  - Empty
  - Loaded
  - Armed
- ✗ Cleaning
- ✗ Chemical Resistance
- Lifecycle protocol
  - Time
  - Frequency
  - Skin model
  - Number of injections
  - Assessment method
    - Laboratory
      - Pressure and Velocity Curves
      - Reproducibility and Repeatability
    - Clinical Data
- EMI/RF/Vibration

### **III Scientific Understanding**

- Injection Pressure Profile
- Injection Velocity Profile
- Injection Duration
  - Injection phase
  - Relaxation phase
- Depth and Dispersion

### **IV Labeling**

### **V Product Options**

- Single versus Multi-dose
- Container closure
- Filling method
- Dosing Adjustments or Increments
- Consumer Product
- Clinical Product

### **VI User Interactions**

- Contact Pressure with Skin
- Orientation / Contact Angle with Skin
- Performance as f(device orientation)
- Portability
- Noise/Discretion
- Size and Weight

## VII WG3 Adhoc 1 Perspective

### Jet Injector General Requirements

<b>Requirement</b>	When the Injector is ready for injection, the medicinal product container shall allow visibility of all the deliverable volume.
Compliance	TBD
<b>Requirement</b>	The Injector shall be provided with a residual scale or other means, indicating the remaining amount of medicinal product. It shall be possible to determine whether sufficient medicinal product remains in order to administer the maximum pre-settable dose.
Compliance	TBD
<b>Requirement</b>	The Injector shall indicate the pre-set dose.
Compliance	TBD
<b>Requirement</b>	The Injector shall indicate, at least by visual means, that it is ready for injection. There shall be an indication of the pre-setting procedure by tactile or auditory means.
Compliance	TBD
<b>Requirement</b>	The state of the Injector, when ready to deliver a dose, shall be different to its state when the dose has been delivered. The difference shall be visible.
Compliance	TBD
<b>Requirement</b>	The Injector shall indicate, by visual or auditory or tactile means, that the injection stroke has been completed.
Compliance	TBD
<b>Requirement</b>	If the Injector is designed for variable doses, it shall be designed so that it is impossible to deliver a second dose after delivery of the first dose without a second pre-setting operation.
Compliance	TBD
<b>Requirement</b>	The Injector shall be so designed that it: <ul style="list-style-type: none"><li>- does not allow a larger dose to be pre-set than left in the container or</li><li>- indicates the amount of drug delivered or</li><li>- indicates the amount of drug not delivered of the pre-set dose.</li></ul>
Compliance	TBD